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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,303	05/11/2007	Eric Kandel	70442-PCT-US/JPW/CH	3996

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EXAMINER	
SINGH, ANOOP KUMAR	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
02/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,303	KANDEL ET AL.	
	Examiner	Art Unit	
	ANOOP SINGH	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10, 12-17, 19-20, 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10,12-17,19,20 and 25-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendments to the claims filed 10/29/2007 has been received and entered. Claims 11, 18, 21-24 have been cancelled, while claims 26-27 have been added. Claims 1-10, 12-17, 19-20, 25-27 are under pending in this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, 12-17, drawn to a method of a method for treating a subject afflicted with a fear-related disorder comprising administering to the subject a therapeutically effective amount of a gastrin- releasing peptide receptor agonist.

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Group II, claims 19-20, drawn to a nucleic acid comprising gastrin releasing peptide gene and a BAC comprising the nucleic acid.

Group III, claim 25, drawn to an article of manufacture comprising a packaging material having therein a gastrin releasing peptide receptor agonist and a label indicating a use for the agonist in treating and or inhibiting the onset of a fear related disorder in a subject.

Group IV, claims 26-27, drawn to a transgenic animal and a method of producing a transgenic animal whose amygadaloid cell specifically express an exogenous polypeptide.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The technical feature linking group I-IV is a gastrin releasing peptide receptor agonist for the treatment of fear related disorder.

Yamada et al (Mol Psychiatry. 2002; 7(1): 113-117, IDS) teach a method of administering Bombesin (BN) like peptides that are involved in the regulating of a wide variety of behaviors. Yamada et al also disclose a method of assessing BN-like peptide/receptor in emotional and or anxiety related behavior in L-D box test and elevated plus maze test to assess the risk assessment behavior (pp 114, table 1; pp 115, col.1, para 2). Yamada et al further teach BN like peptides/receptors may play a role in modulating emotions including some form of anxiety while Shumyatsky et al (Cell. 2002 Dec 13; 111(6): 905-18, IDS) teach GRP gene encoding gastrin-releasing peptide is expressed in lateral nucleus of the amygdale and in the regions that convey fearful auditory information to the lateral nucleus. Shumyatsky et al disclose that GRPR-deficient mice shows decreased inhibition of principal neurons by the inter neurons, enhanced long-term potentiation (LTP), and more persistent long-term fear memory. Shumyatsky et al provide evidence that GRP and its neural circuitry operate as a negative feedback regulating fear and establish a causal relationship between *Grpr* gene expression, LTP, and amygdala-dependent memory for fear (abstract). It is noted that Shumyatsky et al emphasize the importance of identification of components of GRP/GRPR as a potential target for potential treatment of anxiety disorder (pp 915, col.2, para 2). Darker et al (J Pept Sci. 2001, 7(11): 598-605, IDS) teach potent and selective synthetic peptide that are gastrin releasing peptide receptor (GRPR; BB-2) agonist (abstract and table 2). Darker et al also emphasize that these selective and potent agonist should be further studied for their role in biological processes (pp 603, 2 col. para 3). Thus, at the time claimed invention was made; an artisan of skill would have been motivated to treat a subject suffering from fear related disorder by administering the agonist of GRPR as disclosed by Darker in a method disclosed by Yamada with reasonable expectation of successfully treating fear or anxiety related disorder by administering the potent and selective GRPR agonist. Therefore, the instant technical feature does not contribute over prior art.

In addition, the inventions are distinct, each from other because of the following reasons: In the instant case, method of treating a disorder by administering a subject effective amount of GPCR agonist requires consideration for route and site of administration of agonist in a predictable animal model. The nucleic acid and kit comprising GPCR agonist is distinct from method of treatment because nucleic acid could be used to transform cell or make transgenic animal, while kit could be used in a diagnostic kit. In contrast, transgenic animal could be used as disease model or for screening candidate test agent. Thus, each have different patentability considerations that involves distinct and different composition and or method steps and therefore, searching for distinct method steps

and composition will not be coextensive and will require separate and independent searches in the patent and non-patent literature.

Each invention is directed to distinct goal, which comprises the use administering an agonist, nucleic acid, a kit or transgenic animal in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or

otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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